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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,049

01/18/2006

David M. Hammerbeck

C1271.70077US00

1834

23628 7590 01/28/2010
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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

01/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,049	Applicant(s) HAMMERBECK ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11, 12, 15-21, 35-37, 39, 41, 43 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 36-38, 41, 43 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11, 12, 15-21 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/22/09, 11/12/08, 8/11/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of response to election/restriction requirement filed 11/04/09, request for extension of time filed 11/04/09, IDS filed 10/22/09, 11/12/08 and 8/11/06 and preliminary amendment filed 1/18/06. Claims 1-7, 11, 12, 15-21, 35-37, 39, 41, 43 and 45 are pending. Claims 3-5, 11, 15, 37, 39, 41, 43 and 45 have been amended (preliminary amendment of 1/18/06). Claims 8-10, 13, 14, 22-34, 38, 40, 42, 44 and 46-48 were canceled by the preliminary amendment of 1/18/06.

Priority

The examiner acknowledges this application as a 371 of PCT US04/25277 filed 08/05/04 and which claims benefit of provisional application 60/493,109 filed 08/05/2003.

Election/Restrictions

1. Applicant's election of Group I, claims 1-7 (8-10 canceled in the preliminary amendment), 15-21 and 35 in the reply filed on 11/04/09 is acknowledged. Because applicant did not distinctly and specifically state that the election was made with traverse or without traverse and did not point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicant has also elected compound N-{2-[4-amino-2-(ethoxymethyl)-1H-imidazo[4,5-c]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide as the specific immune response modifier.

Claim Objections

3. Claims 4-8 are objected to because of the following informalities:

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4. Claims 6 fails to further limit claim 5 where the hydrophilic viscosity enhancers are limited to polysaccharide gum, acrylic acid polymer. But claim 6 does not limit those polymers but rather generically defines what the hydrophilic viscosity enhancers are and the recitation in claim 6 is broader than the recitation of claim 5, which does not further limit claim 5.

5. Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only.

6. The “any one of claim 1” derived from the amendment is improper. It appears that applicant may have intended to cross-out “any one of” See MPEP § 608.01(n).

7. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-7, 15-21 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Skwierczynski et al. (US 6,245,776).

10. Skwierczynski discloses composition comprising immune response modifier and carrier components (abstract; column 14, lines 7, 15, 24, 44, 58-67; column 15, lines 1-44). Immune response modifier listed in columns 3-13 meets the immune response modifier of claims 1, 2, 11, 12, 15-21 and 35. Example 1 contains xanthan gum that meets the limitation of claims 1 and 3-7. The xanthan gum in Example 1, Table 1 is present at 0.5%, which is at least 0.1%.

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Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-7, 15-21 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Crooks et al (US 6,331,539) or Miller et al. (US 6,083,505) in view of Skwierczynski et al (US 6,245,776).

14. Crooks: Crooks discloses pharmaceutical composition that comprises the immune response modifier of claims 1, 2, 11, 12, 15-21 and 35 and carrier components (abstract, column 2, lines 8-14; column 14, lines 26-45 and claims 26-28).

15. Crooks does not teach the pharmaceutical carriers of claims 1 and 3-7.

16. However, immune response modifiers of the types disclosed by Crooks have been formulated with xanthan gum at 0.5% (see the whole document with emphasis on abstract; column 14, lines 7, 15, 24, 44, 58-67; column 15, lines 1-44).

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17. Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the immune response modifier of Crooks can be formulated with xanthan gum because the immune response modifier have been successfully formulated with xanthan gum according to Skwierzynski.

18. Miller: Miller discloses pharmaceutical composition comprising immune response modifier of claims 1, 2, 11, 12, 15-21 and 35 and carriers (see column 3, lines 4-11; column 8, lines 61-67; claims 1 and 12).

19. Miller does not teach the pharmaceutical carriers of claims 1 and 3-7.

20. However, immune response modifiers of the types disclosed by Miller have been formulated with xanthan gum at 0.5% (see the whole document with emphasis on abstract; column 14, lines 7, 15, 24, 44, 58-67; column 15, lines 1-44).

21. Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the immune response modifier of Miller can be formulated with xanthan gum because the immune response modifier have been successfully formulated with xanthan gum according to Skwierzynski.

22. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618